

Listing of Claims Per 37 C.F.R. §1.121

Claims 1 - 22. (canceled)

23. (currently amended) The cranial orthosis for preventing positional plagiocephaly in infants as set forth in ~~claim 24, claim 40,~~ wherein the contoured interior surface of the helmet appliance is dimensioned to provide overlapping coverage over substantially all of the occipital area of the infant's head ~~when the helmet is worn in the protective position.~~

Claim 24. (canceled)

25. (currently amended) The cranial orthosis for preventing positional plagiocephaly in infants as set forth in ~~claim 24, claim 40,~~ the molded appliance including interior surfaces that are contoured and conformed in shape to the surface curvatures of the occipital, temporal and parietal areas, respectively, of a human infant cranium having normal size, shape and symmetry of a healthy infant of given age and gender.

26. (currently amended) The cranial orthosis for preventing positional plagiocephaly in infants as set forth in ~~claim 24~~, claim 40, characterized in that the pocket is slightly oversized relative to the head of an infant to be protected, thereby allowing the infant's head to turn from side-to-side without imposing binding engagement of the molded appliance against the developing head area.

27. (currently amended) The cranial orthosis for preventing positional plagiocephaly in infants as set forth in ~~claim 24~~, claim 40, wherein the molded appliance is loosely fitted relative to the head of an infant to be protected, whereby when an infant's head is received in the protective pocket and the infant is resting on a sleep surface in a supine position, the contoured interior surfaces provide support for the areas to be protected substantially without imposing focused torque forces on the infant's occiput.

28. (currently amended) The cranial orthosis for preventing positional plagiocephaly in infants as set forth in ~~claim 24~~, claim 40, wherein the protective cavity pocket is sized to provide nesting engagement of the soft developing area against the layer covering the conformed interior surface, whereby when the infant's head is received in the protective pocket and the infant is resting on a sleep surface in a supine position, the infant's head weight forces are distributed substantially uniformly over the conformed interior surface- covering layer that engages the soft developing area.

Claims 29-34. (canceled)

35. (currently amended) The cranial orthosis for preventing positional
plagiocephaly in infants as set forth in ~~claim 24~~ claim 40, wherein the molded
appliance is generally U-shaped in cross section and has bilateral symmetry.

36. (currently amended) The cranial orthosis for preventing positional
plagiocephaly in infants as set forth in ~~claim 24~~, claim 40, wherein the molded
appliance comprises a unitary molding formed of a plastic resin material.

37. (currently amended) The cranial orthosis for preventing positional
plagiocephaly in infants as set forth in ~~claim 24~~, claim 40, wherein the molded
appliance comprises a headband formed of a plastic resin material.

38. (currently amended) The cranial orthosis for preventing positional
plagiocephaly in infants as set forth in ~~claim 24~~, claim 40, wherein the molded
appliance comprises a helmet formed of a plastic resin material.

39. (canceled)

40. (Original) The ~~cranial orthosis for preventing positional plagioccephaly in infants as set forth in claim 24, including~~

A cranial orthosis for preventing acquired plagioccephaly in infants having a soft developing head area to be protected, comprising:

a molded appliance having an interior surface that is conformed in shape to the surface curvature of a human infant cranium and operable to accommodate infant head growth; and

two or more layers of soft, flexible material releasably disposed in overlapping nested relation and covering lining the conformed interior surface of the appliance thereby defining a protective pocket for receiving an infant's head, the protective pocket being sized to provide a close, non-compressive fit about the developing head area to be protected, and whereby the lining layers can be removed one at a time to accommodate head growth.

41. (currently amended) The cranial orthosis for preventing positional plagioccephaly in infants as set forth in claim 40, wherein the lining layers are provided in different colors that correspond with different fronto-occipital circumference increments.

Claim 42. (canceled)

43. (currently amended) ~~The method for preventing postural plagioccephaly in infants as set forth in claim 42, including the steps:~~

A method for preventing postural plagioccephaly in a human infant having a cranium that is substantially normal in size and curvature for its age and gender, comprising the steps:

providing a protective appliance in the form of a shell, headband or helmet having an interior surface that is operable to accommodate infant head growth and contoured to conform to the head shape of a healthy human infant of the same age and gender, thereby defining a pocket for receiving the head of an infant having a soft developing area to be protected, wherein the pocket is sized to provide a close, non-interfering fit about the infant's head when the appliance is worn by the infant in a protective position in which the contoured interior surface is disposed in facing relation to the soft developing area to be protected;

lining the interior surface of the protective headband with one or more layers of soft, spongy material or fabric material;

supporting the infant's head within the protective appliance while the infant is resting on a sleep surface in the supine position; and

removing one or more of the lining layers to accommodate growth of the infant's head.

44. (currently amended) The method for preventing postural plagiocephaly in infants as set forth in ~~claim 42~~, claim 43, including the steps:

- (a) providing an inventory of the protective appliances, each of the appliances having a pocket conforming substantially in size and shape to the cranium of a healthy human infant of given age and gender, the inventory comprising a plurality of the protective appliances of various cavity sizes that are indexed according to age, gender and average fronto-occipital circumference values tabulated for the general infant population;
- (b) measuring the fronto-occipital circumference of the infant's head; and
- (c) selecting for the infant's treatment a protective appliance from the inventory that most closely matches the infant's head size, age and gender.

Claim 45. (canceled)

46. (currently amended) The method for preventing postural plagiocephaly in infants as set forth in ~~claim 45~~, claim 43, including the step:

allowing the infant's head weight forces to spread substantially uniformly across the facing portion of the conformed interior surface lining that is engaged by the soft developing areas while the infant is in the supine position.

47. (currently amended) The method for preventing postural plagiocephaly in infants as set forth in claim 45, claim 43, wherein the conformed interior surface lining forms the boundary of a protective pocket in which the infant's head is received, including the step of sizing the protective pocket to provide a close, non-interfering fit of the conformed interior surface lining adjacent to the developing head area.

48. (currently amended) The method for preventing postural plagiocephaly in infants as set forth in claim 45, claim 43, wherein the conformed interior surface lining forms the boundary of a protective pocket in which the infant's head is received, including the step of sizing the protective pocket to provide nesting engagement of the developing head area against the conformed interior surface lining.

49. The method for preventing postural plagiocephaly in infants as set forth in claim 45, claim 43, wherein the conformed interior surface lining forms the boundary of a protective pocket in which the infant's head is received, including the step of sizing the protective pocket to provide a close, non-compressive fit of the conformed interior surface lining about the developing head area.

50. (currently amended) The method for preventing postural plagiocephaly in infants as set forth in ~~claim 45~~, claim 43, wherein the conformed interior surface lining forms the boundary of a protective pocket in which the infant's head is received, including the step of sizing the protective pocket to provide a slightly oversized fit relative to the head of an infant to be protected whereby the orthosis can be worn without imposing binding engagement of the orthosis against the developing area of the infant's head.